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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Sylvie Pridmore-Merten

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EXAMINER

CLARK, AMY LYNN

ART UNIT

PAPER NUMBER

1655

NOTIFICATION DATE

DELIVERY MODE

07/02/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/526,577	Applicant(s) PRIDMORE-MERTEN ET AL.	
	Examiner Amy L. Clark	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 9-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>09/14/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

Election/Restrictions

Claims 1-21 are currently pending.

Applicant's election with traverse of Group I, claims 1-8 and 17 and of carnitine and antioxidant, human hair, dietary supplement and food in the reply filed on 04/21/2008 is acknowledged. The traversal is on the grounds that the inventions require the same field of search and that keeping the inventions together will diminish the workload of the Office and Applicants.

This is not found persuasive because the MPEP states,

“An international application should relate to only one invention or, if there is more than one invention, the inclusion of those inventions in one international application is only permitted if all inventions are so linked as to form a single general inventive concept (PCT Rule 13.1). With respect to a group of inventions claimed in an international application, unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. The expression “special technical features” is defined in PCT Rule 13.2 as meaning those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art. The determination is made on the contents of the claims as interpreted in light of the description and drawings (if any).

Whether or not any particular technical feature makes a “contribution” over the prior art, and therefore constitutes a “special technical feature,” should be considered with respect to novelty and inventive step. For example, a document discovered in the international search shows that there is a presumption of lack of novelty or inventive step in a main claim, so that there may be no technical relationship left over the prior art among the claimed inventions involving one or more of the same or corresponding special technical features, leaving two or more dependent claims without a single general inventive concept.”

See also MPEP 1893.03(d):

“When making a lack of unity of invention requirement, the examiner must (1) list the different groups of claims and (2) explain why each group lacks unity with each other group (i.e., why there is no single general inventive concept) specifically describing the unique special technical feature in each group”.

The principles of unity of invention are used to determine the types of claimed

Art Unit: 1655

subject matter and the combinations of claims to different categories of invention that are permitted to be included in a single international or national stage patent application. See MPEP § 1850 for a detailed discussion of Unity of Invention. The basic principle is that an application should relate to only one invention or, if there is more than one invention, that applicant would have a right to include in a single application only those inventions which are so linked as to form a single general inventive concept.

A group of inventions is considered linked to form a single general inventive concept where there is a technical relationship among the inventions that involves at least one common or corresponding special technical feature. The expression special technical features is defined as meaning those technical features that define the contribution which each claimed invention, considered as a whole, makes over the prior art. For example, a corresponding technical feature is exemplified by a key defined by certain claimed structural characteristics which correspond to the claimed features of a lock to be used with the claimed key.”

Since the Application is an international application, the basis of the restriction requirement is not on the field of search but whether the invention lacks unity. Since the invention lacks unity, as set forth in the previous Office Action, the restriction requirement is deemed proper.

In response to Applicant's argument that all claims should be prosecuted in the same application to lessen the workload, please note the following. The Examiner appreciates Applicant's concern, however, each application is treated based upon the invention that Applicant is claiming. A restriction requirement and species election help to expedite the examination of each application accordingly by indicating to the Examiner what invention Applicant would like the Examiner to search, which expedites the examination process considerably and allows the Examiner to perform a thorough search of Applicant's desired invention.

Therefore, the requirement is still deemed proper and is therefore made FINAL.

Claims 9-21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and specie, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 04/21/2008.

Claims 1-8 are currently under examination.

Claim Objections

Claim 6 is objected to because of the following informalities: please insert a after "of" in line 2. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "the cell" in the cell. There is insufficient antecedent basis for this limitation in the claim.

The term "natural sources" in claim 2, line 4 is a relative term which renders the claim indefinite. The term "natural sources" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-8 are rejected under 35 U.S.C. 102(a) as being anticipated by Hamilton (N, WO 0211717 A1, Abstract only).

Hamilton teaches a skin care composition comprising an antioxidant and carnitine effective against hair loss and capable of stimulating hair growth, which reads on topical pharmaceutical, comprising carnitine in an amount of 1 w/w % and creatine in an amount of 0.9 w/w % and further comprising an antioxidant, wherein the antioxidant is α -lipoic acid in an amount of 1 w/w % and deionized water, which reads on an orally acceptable carrier

Therefore, the reference anticipates the instantly claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Borgonovo et al. (O, WO 0053176 A1).

Borgonovo teaches a dietary composition for treating atypical dermatitis, psoriasis, erythemas and hair loss comprising 2-20% of each of thioctic acid (which is synonymous with α -lipoic acid) and cysteine, wherein cysteine may be in the form of cystine and further comprising 2-8% of each of the following ingredients: carnitine, vitamin C, Vitamin E, phytoestrogens extracted from soybeans (See page 5, lines 33-35

Art Unit: 1655

bridging page 6, lines 1-20). Borgonovo further teaches that the composition may be administered in the form of pills, water, confectionaries (which reads on food) and syrups and that the composition can further comprise vehicles for the compositions, where in the vehicle may be olive oil or sunflower oil (among others), which reads on orally acceptable (See page 7). Borgonovo further teaches several examples of administering compositions comprising tioctic acid (which is synonymous with α -lipoic acid) and cysteine to humans.

Borgonovo does not expressly teach the combination of carnitine with antioxidants; however, it would have been obvious to one of ordinary skill in the art at the time the invention was made to treat hair loss with the composition taught by Borgonovo.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine tioctic acid (which is synonymous with α -lipoic acid) and cysteine, wherein cysteine may be in the form of cystine with carnitine, vitamin C, vitamin E and phytoestrogens extracted from soybeans to make the claimed invention, since the beneficial effects of tioctic acid (which is synonymous with α -lipoic acid) and cysteine, wherein cysteine may be in the form of cystine with carnitine, vitamin C, vitamin E and phytoestrogens were known to be useful for treating hair loss in humans.

Finally, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to combine the following beneficial skin care components to gain the benefits of individual components as part of a composition for the treatment of hair loss: tioctic acid (which is synonymous with α -lipoic acid) and

Art Unit: 1655

cysteine, wherein cysteine may be in the form of cystine with carnitine, vitamin C, vitamin E and phytoestrogens extracted from soybeans to make a composition for treating hair loss because at the time the invention was made, tiotic acid (which is synonymous with α -lipoic acid) and cysteine, wherein cysteine may be in the form of cystine with carnitine, vitamin C, vitamin E and phytoestrogens extracted from soybeans were known to be combinable for the same purpose, as clearly taught by Borgonovo.

Based upon the beneficial teachings of the cited references, the skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy L. Clark whose telephone number is (571)272-1310. The examiner can normally be reached on Monday to Friday between 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1655

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ALC
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Amy L. Clark
June 20, 2008

/Michele Flood/
Primary Examiner, Art Unit 1655